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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,732	12/20/2001	Thomas J. Bormann	440525/PALL	9021

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LEYDIG VOIT & MAYER, LTD
700 THIRTEENTH ST. NW
SUITE 300
WASHINGTON, DC 20005-3960

EXAMINER

MENON, KRISHNAN S

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,732

Applicant(s)

BORMANN ET AL.

Examiner

Krishnan S Menon

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-22 and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-22 and 31-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1723

DETAILED ACTION

Claims 1-13, 15-22 and 24-34 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, 15-22 and 31-34, drawn to a filter and a filter device for processing biological fluids.

Group II, claim(s) 24-30, drawn to method of processing a biological fluid.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of claim 1, filter element with specified N to O ratio which is shown by the prior art EP 0 606 46, an X reference, to lack novelty or inventive step and thus does not define a contribution over the prior art.

During a telephone conversation with Mr. Jeremy Jay, attorney of record, on 6/26/03 a provisional election was made without traverse to prosecute the invention of group I, claims 1-22 and 31-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1723

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,7-10,12,16 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by EP-0 606 646 A1.

EP-646 teaches a filter for processing biological fluids comprising a filter element having a surface N/O ratio within the range of 0.01 to 1.0, and another filter having the surface hydroxylated as in claim 1; additional elements having N/O ratio within 0.01 – 1.0 as in claim 2; element hydroxylated is also aminated as in claim 7 and 8; the surface N/O ratio is within 0.2 and 1.0 as in claim 9; hydroxylated surface could include carboxyl groups as in claim 10; the surface having N/O ratio within 0.01 to 1.0 could have a greater number of carboxylate groups relative to the bulk as in claim 31. (Abstract, page 5 lines 41-58, page 6 lines 1-21, examples). EP-646 teaches a filter device with a filter of claim 1 with an inlet and an outlet as in claim 16 (page 11 lines 47-48, examples).

The element will have a negative Zeta potential at a physiological pH as in claim 11 because it is a material property[[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of

Art Unit: 1723

proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). The elements will have a CWST as in claim 12, which is also a material property.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 15-22 and 31-34, rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0267 286 A1 in view of EP 0630 675 A1.

EP-286 teaches a filter comprising one or more elements having N/O ratio within 0.01-1.00 (or 0.2-1.0 – claim 9), the elements also surface-hydroxylated relative to the bulk as in claims 1-9 and 31-34. Element hydroxylated is also aminated as in claim 7 and 8. The hydroxylated surfaces include

Art Unit: 1723

carboxyl groups as in claim 10 (abstract, page 1, 7,9 and 10. Re the N/O ratio, the molar concentrations of the functional monomers would give that ratio-page 23).

EP-286 does not teach separate elements, one set having N/O ratio and another set having excess surface hydroxyl groups as in the instant claims, and separate elements having excess surface carboxyl and excess surface hydroxyl groups as in claim 32. EP 675 teaches filter for filtering and separating leukocytes and platelets having elements (layers) with excess surface N/O and carboxy groups (page 5 lines 9-18), and other elements having excess surface hydroxy groups (page 7 lines 27-56). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of EP 675 in the teaching of EP 286 for a filter to filter and separate leukocytes and platelets from plasma, as taught by EP 675. One would use the teaching of EP 675 to modify the teachings of EP 286 for filtration from plasma of leukocytes and platelets with improved separation of platelets and leukocytes.

Re claims 11-13 and 15, zeta potential as in claim 11, and CWST as in claims 12, 13 and 15 are all material properties, and would be similar for similar materials. [[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 16-22 add further elements as follows: EP teaches a housing with inlet and outlet as in claim 16, plasma passes through and leukocytes and platelets do not as in claim 17; re C3a as in claims 18,19 and 22, similar filter structure would give similar results for C3a as obtained by the

Art Unit: 1723

applicant. Re leukocyte and platelet counts in the plasma product, this factor would depend on the counts in the original plasma in addition to the efficiency of the filter (see table 1 of EP-286 and table 2 of EP 675).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gsell et al (US 5,258,127 – hydroxylated surface with CWST values and plasma transmission; Pall (US 4,880,548) – HEMA/MMA treated surface, CWST, leukocyte depletion with platelet transmission.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner
July 11, 2003

Walker
W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700